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PTO/SB/08A (08-00)

Substitute for Form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	09/757,673
				Filing Date	January 10, 2001
				First Named Inventor	James M. Wilson et al
				Group Art Unit	1632
				Examiner Name	J. Martin — R. Shulda
Sheet	1	of	11	Attorney Docket Number	GNVPN.019B1USA

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
RRS	AA	5,139,941	A	N. Muzycka	08/18/1992	—
	AB	5,173,414	A	J. Lebkowski	12/22/1992	—
	AC	5,478,745	A	R. Samulski	12/26/1995	—
	AD	5,753,500	A	T. Shenk	05/19/1998	—
RRS	AE	5,252,479	A	A. Srivastava	10/12/1993	—

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴				
RRS	AL	WO	WO96/00587	A R. Samulski w, po	01/11/1996	—	
	AM	WO	WO95/34670	A P. Johnson w, po	12/21/1995	—	
	AN	WO	WO95/33824	A L. Alexander w, po	12/14/1995	—	
RRS	AO	WO	WO95/28493	A M. Kaplitt w, po	10/26/1995	—	
RRS	AP	WO	WO95/23867	A P. Deneffe w, po	09/08/1995	—	

Examiner Signature	RRS	Date Considered	11/19/01
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RRS	AF	5,354,678	A	J. Lebkowski	10/11/1994	_____
✓	AG	5,436,146	A	T. Shenk	07/25/1995	_____
✓	AH	5,474,935	A	S. Chatterjee	12/12/1995	_____
↓	AI	5,858,351	A	G. Podskoff	01/12/1999	_____
RRS	AJ	5,789,390	A	V. Descamps	08/04/1998	_____

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		Office ³	Number ⁴			
RRS	AQ	WO	WO95/20671	A V. Descamps WIPO	08/03/1995	_____
✓	AAL	WO	WO95/14771	A R. Kotin WIPO	06/01/1995	_____
✓	AAM	WO	WO95/13392	A J. Trempe WIPO	05/18/1995	_____
✓	AAN	WO	WO95/07995	A R. Philip WIPO	03/23/1995	_____
RRS	AAO	WO	WO95/06743	A J. Dong WIPO	03/09/1995	_____

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Examiner Name	J. Martin R. Shukla														
Sheet	3	of	11	Attorney Docket Number	GNVPN.019B1USA										

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		Number	Kind Code ³ (if known)			
RRS	AK	5,116,739	A	Y. Teranishi	05/26/1992	✓
✓	AAA	5,672,685	A	W. Matthew	09/30/1997	_____
✓	AAB	5,693,531	A	Chiorini	12/02/1997	_____
↓	AAC	6,093,392	A	K. High	07/25/2000	_____
RRS	AAD	5,585,254	A	I. Maxwell	12/17/1996	_____

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		Office ³	Number ⁴	Kind Code ³ (if known)				
RRS	AAP	WO	WO94/20517	A	J. Glorioso WIPO	09/15/1994	_____	✓
✓	AAQ	WO	WO93/24641	A	B. Carte WIPO	12/09/1993	_____	✓
✓	BL	WO	WO91/18088	A	S. Chatterjee WIPO	11/28/1991	_____	✓
↓	BM	WO	WO96/18727	A	G. Natsoulis WIPO	06/20/1996	_____	✓
RRS	BN	WO	WO96/12010	A	G. Holscher WIPO	04/25/1996	_____	✓

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				Examiner Name	J. Martin R. Shulca
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RRS	AAE	5,866,552	A	J. Wilson	02/02/1999	_____

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		Office ³	Number ⁴				
RRS	BO	WO	WO96/17947	A J. Allen w.RO	06/13/1996	_____	
	BP	WO	WO97/26337	A G. Podskoff w.RO	08/24/1997	_____	
	BQ	WO	WO96/40272	A X. Xiao w.RO	12/19/1996	_____	
↓	BBL	WO	WO97/26336	A G. Podskoff w.RO	07/24/1997	_____	
RRS	BBM	WO	WO94/13788	A R. Samulski w.RO	06/23/1994	_____	

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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
RRS	BBN	WO	WO97/12050	A	M. Kaplitt w1P0	04/03/1997	_____	
RRS	BBO	AU	27902/92	A	M. Perricaudet ^{Australia}	04/27/1993	_____	
RRS	BBP	WO	WO96/14837	A	A. McClelland w1P0	05/23/1996	_____	

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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS					
Examiners Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
RRS	AR	D. COOVERT et al, "Gene Therapy for Muscle Diseases", Current Opinion in Neurology, 7:463-470 (1994)			
	AS	R. HERZOG et al, "Stable Gene Transfer and Expression of Human Blood Coagulation Factor IX After Intramuscular Injection of Recombinant Adeno-Associated Virus", Proc. Natl. Acad. Sci. USA, 94:5804-5809 (May, 1997)			
	AT	K. FISHER et al, "Recombinant Adeno-Associated Virus for Muscle Directed Gene Therapy", Nature Medicine, 3(3):306-312 (March, 1997) [Fisher I]			
	AU	P. KESSLER et al, "Gene Delivery to Skeletal Muscle Results in Sustained Expression and Systemic Delivery of a Therapeutic Protein", Proc. Natl. Acad. Sci. USA, 93:14082-14087 (November, 1996)			
	AV	D. RUSSELL et al, "Adeno-Associated Virus Vectors Preferentially Transduce Cells in S Phase", Proc. Natl. Acad. Sci. USA, 91:8915-8919 (September, 1994)			
	AW	J. WOLFF et al, "Direct Gene Transfer into Mouse Muscle in Vivo", Science, 247:1465-1468 (March 23, 1990)			
	AX	H. BLAU et al, "Localization of Muscle Gene Products in Nuclear Domains: Does this Constitute a Problem for Myoblast Therapy?", Adv. Exp. Med. Biol., 280:167-172 (1990)			
RRS	AY	N. MUZYCZKA, "Use of Adeno-Associated Virus as a General Transduction Vector for Mammalian Cells", Curr. Topics Microbiol. Immunol., 158:97-129 (1992)			

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<i>RPS</i>	AZ	R. SAMULSKI et al, "Targeted Integration of Adeno-Associated Virus (AAV) into Human Chromosome 19", EMBO J., 10(12):3941-3950 (1991) [Samulski I]			
<i>✓</i>	AAR	R. KOTIN, "Prospects for the Use of Adeno-Associated Virus as a Vector for Human Gene Therapy", Human Gene Therapy, 5:793-801 (1994) [Kotin I]			
<i>✓</i>	AAS	R. KOTIN et al, "Site-Specific Integration by Adeno-Associated Virus", Proc. Natl. Acad. Sci. USA, 87:2211-2215 (March, 1990) [Kotin II]			
<i>✓</i>	AAT	K. FISHER et al, "Transduction with Recombinant Adeno-Associated Virus for Gene Therapy is Limited by Leading-Strand Synthesis", J. Virol., 70(1):520-532 (January, 1996) [Fisher II]			
<i>✓</i>	AAU	C. HODGSON, "Advances in Vector Systems for Gene Therapy", Exp. Opin. Ther. Patents, 5(5):459-468 (1995)			
<i>✓</i>	AAV	R. SAMULSKI et al, "Helper-Free Stocks of Recombinant Adeno-Associated Viruses: Normal Integration does not Require Viral Gene Expression", J. Virol., 63(9):3822-3828 (September, 1989) [Samulski II]			
<i>RPS</i>	AAW	M. WEITZMAN et al, "Recruitment of Wild-Type and Recombinant Adeno-Associated Virus into Adenovirus Replication Centers", J. Virol., 70(3):1845-1854 (March, 1996)			
	AAX	S. GOODMAN et al, "Recombinant Adeno-Associated Virus-Mediated Gene Transfer into Hematopoietic Progenitor Cells", Blood, 84(5):1492-1500 (September, 1994)			

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<i>RPS</i>	AAY	B. YAKOBSON et al, "Replication of Adeno-Associated Virus in Synchronized Cells without the Addition of a Helper Virus", <i>J. Virol.</i> , 61(4):972-981 (April, 1987)			
	AAZ	E. KREMER et al, "Adenovirus and Adeno-Associated Virus Mediated Gene Transfer", <i>British Medical Bulletin</i> , 51(1):31-44 (1995)			
	BR	E. RAZ et al, "Systemic Immunological Effects of Cytokine Genes Injected into Skeletal Muscle", <i>Proc. Natl. Acad. Sci. USA</i> , 90:4523-4527 (May, 1993)			
	BS	K. CULVER et al, "Gene Therapy for Cancer", <i>TIG</i> , 10(5):174-178 (May, 1994)			
	BT	N. MILLER et al, "Targeted Vectors for Gene Therapy", <i>FASEB J.</i> , 9:190-199 (February, 1995)			
	BU	E. MARSHALL, "Gene Therapy's Growing Pains", <i>Science</i> , 269:1050-1055 (August 25, 1995)			
	BV	M. KAPLITT et al, "Long-Term Gene Expression and Phenotypic Correction Using Adeno-Associated Virus Vectors in the Mammalian Brain", <i>Nature Genetics</i> , 8:148-154 (October, 1994)			
	BW	K. MARCH et al, "The Adeno-Associated Virus as a Gene Transfer Vector for Human and Non-Human Vascular Smooth Muscle Cells", <i>Clinical Research</i> , 40(2):358A (1992)			
<i>RPS</i>	BX	X. XIAO et al, "Efficient Long-Term Gene Transfer into Muscle Tissue of Immunocompetent Mice by Adeno-Associated Virus Vector", <i>J. Virol.</i> , 70(11):8098-8108 (November, 1996) [Xiao I]			

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<i>RRS</i>	BY	X. XIAO et al, "Adeno-Associated Virus (AAV) Vectors for Gene Transfer", Advanced Drug Delivery Reviews, 12:201-215 (1993) [Xiao II]			
	BZ	S. ORKIN et al, "Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy", NIH Press, pp. 1-40 (December 7, 1995)			
	BBR	A. LAFONT et al, "Which Gene for Which Restenosis?", The Lancet, 346:1442-1443 (December 2, 1995)			
	BBS	R. BARTLETT et al, "A Plasmid Expression Vector Based on the Adeno-Associated Virus (AAV) Containing Muscle-Specific Transcription Elements for Expression of Therapeutic Proteins", Amer. J. Human Genet., 57(Suppl. 4):A235 (October, 1995) (Abstract #1362)			
	BBT	M. EINERHAND et al, "Regulated High-Level Human β-globin Gene Expression in Erythroid Cells Following Recombinant Adeno-Associated Virus-Mediated Gene Transfer", Gene Therapy, 2(5):336-343 (July, 1995)			
	BBU	DIRK GRIMM et al, "Progress in Adeno-Associated Virus Type 2 Vector Production: Promises and Prospects for Clinical Use", Human Gene Therapy, 10:2445-2450 (October 10, 1999)			
<i>RRS</i>	BBV	RONALD G. CRYSTAL, "Transfer of Genes to Humans: Early Lessons and Obstacles to Success", Science, 270:404-410 (October 20, 1995)			

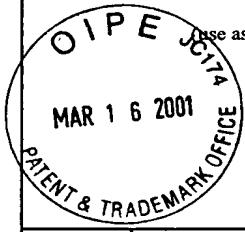
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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
Examiners Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
RRS	BBW	SIHONG SONG et al, "Sustained Secretion of Human Alpha-1-Antitrypsin from Murine Muscle Transduced with Adeno-Associated Virus Vectors", Proc. Natl. Acad. Sci. USA, 95:14384-14388 (November, 1998)		
	BBX	W. FRENCH ANDERSON, "Human Gene Therapy", Nature, 392:25-30 (April 30, 1998)		
	BBY	P.E. MONAHAN et al, "AAV Vectors: Is Clinical Success on the Horizon?", Gene Therapy, 7:24-30 (2000)		
	BBZ	ROLAND W. HERZOG et al, "Adeno-Associated Virus-Mediated Gene Transfer of Factor IX for Treatment of Hemophilia B by Gene Therapy", Thrombosis and Haemostasis, 82(2):540-546 (1999)		
	CR	MELINA KIBBE et al, "Gene Therapy and Vascular Disease", Advances in Pharmacology, 46:85-150 (1999)		
	CS	B. FANG et al, "Gene Therapy for Hemophilia B: Host Immunosuppression Prolongs the Therapeutic Effect of Adenovirus-Mediated Factor IX Expression", Human Gene Therapy, 6:1039-1044 (August, 1995)		
	CT	GYULA ACSADI et al, "Human Dystrophin Expression in mdx Mice After Intramuscular Injection of DNA Constructs", Nature, 352:815-818 (August 29, 1991)		
RRS	CU	VIKRAM S. KASHYAP et al, "Apolipoprotein E Deficiency in Mice: Gene Replacement and Prevention of Atherosclerosis Using Adenovirus Vectors", J. Clin. Invest., 96:1612-1620 (September, 1995)		

Examiner Signature	RRS	Date Considered	11/19/01
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PTO/SB/08B (08-00)

Substitute for Form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>O I P E S C I T A</i> <i>MAR 16 2001</i> <i>PATENT & TRADEMARK OFFICE</i>				Complete If Known	
				Application Number	09/757,673
				Filing Date	January 10, 2001
				First Named Inventor	James M. Wilson et al
				Group Art Unit	1632
				Examiner Name	<i>J. Martin R. Shuhle</i>
Sheet	11	of	11	Attorney Docket Number	GNVPN.019B1USA

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<i>RRS</i>	CV	JAMES M. WILSON et al, "Method for Recombinant Adeno-Associated Virus Directed Gene Therapy", U. S. Patent Application No. 09/237,064, filed January 26, 1999			
	CW	G. GOURAS et al, "Expression of Alzheimer's Disease Associated Genes in vitro and in vivo Using Viral Vectors", Neurobiology of Aging, 17(4):S111 (1996)			
	CX ✓	C. DESURMONT et al, "Complete Atherosclerosis Regression After Human ApoE Gene Transfer in ApoE-deficient/nude Mice", Arterioscler. Thromb. Vasc. Biol., 20(2):435-442 (February, 2000) (PubMed Abstract)			
	CY ✓	J. OSADA et al, "The Value of Apolipoprotein E Knockout Mice for Studying the Effects of Dietary Fat and Cholesterol on Atherogenesis", Curr. Opin. Lipidol, 11(1):25-29 (February, 2000) (PubMed Abstract)			
<i>RRS</i>	CZ ✓	JAMES M. WILSON et al, "Method for Recombinant Adeno-Associated Virus-Directed Gene Therapy", U. S. Patent Application No. 09/242,977, filed February 26, 1999			

Examiner Signature	<i>RRS</i>	Date Considered	<i>11/19/01</i>
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